AF/V

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	:	**(IN TRIPLICATE)**
Jan ENDRIKAT et al.	:	Group Art Unit: 1616
Serial No.: 09/091,665	:	Examiner: Qazi, S.
Filed: September 2, 1998	:	

For: CONTRACEPTIVE PROCESS AND KIT FOR FEMALE MAMMALS, COMPRISING A COMBINATION OF GESTAGEN AND OESTROGEN

BRIEF ON APPEAL UNDER 37 C.F.R. § 41.37

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
ALEXANDRIA, VA 22313-1450

Sir:

Further to the Notice of Appeal filed July 26, 2004, attached herewith are three copies of Appellants' Brief on Appeal. Pursuant to 37 CFR § 41.20(b)(2), attached is a check for $300 for the filing of this Brief.

This is an appeal from the decision of the Examiner finally rejecting claims 4-7 and 14-30.

(1) REAL PARTY IN INTEREST

The application is assigned of record to Schering Aktiengesellschaft, who is the real party in interest herein. The assignment is recorded in Reel 010419/Frame 0837.

(2) RELATED APPEALS AND INTERFERENCES

Appellants, their legal representative and the assignee are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing

on the Board's decision in the instant appeal.

(3) STATUS OF THE CLAIMS

Claims rejected: 3-7 and 14-30;

Claims allowed: None;

Claims canceled: 1, 2, 8-13, and 31-35;

Claims withdrawn: 36-77;

Claims objected to: None;

Claims on Appeal: 3-7 and 14-30. A copy of the claims on appeal is provided in the attached Claim Appendix.

(4) STATUS OF AMENDMENTS AFTER FINAL

Subsequent to the Final Rejection in the Office Action of January 26, 2004, Appellants filed a Amendment under 37 CFR §1.116 on May 26, 2004. In an Advisory Action issued July 9, 2004, the Examiner indicated that the amendments would not be entered. No further amendments have been submitted.

(5) SUMMARY OF THE CLAIMED SUBJETC MATTER

The sole independent claim on appeal is claim 14 (see Claim Appendix). This claim recites a method of contraception in a female mammal. The method comprises administering to the mammal a gestagen over a period of at least 28 days. This period has a first phase and a second phase. The first phase consists essentially of administering an ovulation-inhibiting amount of the gestagen, and the second phase comprises administering an ovulation-inhibiting amount of the gestagen in combination with an amount of a natural estrogen which is effective to achieve regular menstrual-like bleeding. This second phase is the last 5 to 10 days of the period. The first phase is the remainder of period. See, for example, Appellants' specification at page 1, lines 1-7, and page 6, lines 4-9 and 19-27.

In this method, the gestagen is intended to provide contraceptative action, while the natural estrogen builds up their endometrium to thereby provide menstrual-like bleeding as the end of the second phase.

The method exhibits advantages compared to previously known processes for oral

contraception, for example, good cycle control due to the sequential administration of natural estrogen (even for women in premenopause); the contraceptive is well-tolerated owing to the use of a natural estrogen and yields positive effects, especially in bones; good general compatibility, especially liver-compatibility, provided by the use of a natural estrogen; and significantly fewer ethinyl estradiol-related side-effects. See, e.g., page 8, lines 1-19 of Appellants' specification.

(6) GROUNDS OF REJECTION TO BE REVIWED ON APPEAL

The grounds of rejection that are on Appeal are believed to be:

(1) whether claims 3-7 and 14-30 of the application are unpatentable under 35 U.S.C. §112, first paragraph for lack of written description; and

(2) whether claims 3-7 and 14-30 of the application are patentable under 35 U.S.C. §112, first paragraph for lack of enablement;

(3) whether claims 3-7 and 14-30 of the application are patentable under 35 U.S.C. §103 as being obvious in view of the disclosure of Weiner at al.

The rejection for lack of enablement is not set forth in the Final Rejection with any particularity. While the lack of written description rejection and the 35 U.S.C. §103 rejection are clearly set forth with headings, identifying the particular claims being rejected (see pages 4 and 7, respectively, of the January 26, 2004 Office Action), no such heading identifies the lack of enablement rejection. However, beginning at the bottom of page 4 of the Office Action and continuing on through to the top of page 7, the Examiner argues factors to be considered for enablement. Thus, Appellants have assumed that all of the pending, non-withdrawn claims are rejected under 35 U.S.C. §112, first paragraph for lack of enablement.

Further, at page 2 of the January 26, 2004 Office Action it is stated that "claims stand rejected under 35 U.S.C. 112 first and **second** paragraphs, for the reasons stated cited below." (emphasis added) However, no arguments presented in the Office Action in support of an indefiniteness rejection. In fact, indefiniteness is never mentioned in the Office Action. Thus, Appellants have assumed that the reference to 35 U.S.C. §112, second paragraph, was an error.

Further, at the top of page 2 of the Office Action it is stated "Arguments are found persuasive therefore, the 35 U.S.C. 112 rejection is withdrawn." Appellants assume that this statement was in reference to the prior rejection under 35 U.S.C. §112, second paragraph.

(7) APPELLANTS' ARGUMENTS

Rejection under 35 USC §112, first paragraph (Written Description)

Claims 3-7 and 14-30 are presumed to be rejected under 35 U.S.C. § 112, first paragraph on grounds of alleged lack of written description. Appellants' respectfully traversed.

1. Independent Claim 14 and dependent Claims 14, 6, 7, 16-21, and 24

At page 4 of the Final Rejection (January 26, 2004 Office Action), it is asserted that claim 14 does not have any specifics. This rejection seems to be directed to the breadth of Appellants' claim 14. But, this assertion presents no rationale as to why the disclosure does not reasonably convey that Appellants had possession of the subject matter claimed at the filing date of the application. In fact, Appellants' disclosure denies clearly convey possession of the subject matter of claim 14. See, e.g., Appellants' specification at page 1, lines 1-7, and page 6, lines 4-9 and 19-27.

Moreover, claim 14, in fact, does recite specific features of the claimed invention. Claim 14 specifies the host (a female mammal), the components used (a gestagen and a natural estrogen), a time period (at least 28 days) having a first phase and a second phase (which is 5-10 days long), which components are administered during the two phases (a gestagen and a natural estrogen) and the amounts administered (an ovulation-inhibiting amount of a gestagen, and an ovulation-inhibiting amount of a gestagen and a natural estrogen in an amount effective to achieve regular menstrual-like bleeding). These features are expressly described in the specification. Nothing within the rejection refutes this fact.

The Examiner argues that the Weiner et al. article provides details about number of days, what compounds were used, and how much of the compounds were used. However, the question is whether Appellants' disclosure reasonably conveys possession of the subject matter

claimed, not what an article discloses. The disclosure of Weiner is not relevant to the question at hand. In any event, it is common for an article about a particular study to provide very specific details of that study. But, this does not mean that a patent method claim must exhibit the same degree of specificity.

Thus, the rejection of claim 14 on grounds of lack of written description is baseless. The rejection completely fails to present any rationale as to why the subject matter of claim 14 is not reasonably conveyed by Appellants' disclosure. Reversal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

2. Claims 4 and 29

Claims 4 and 29 recite even more details on the compounds used than claim 14. These claims each specify gestagens for use in the method of claim 14. Once again, this concept is expressly described in the specification. See, e.g., page 7. Nothing within the rejection refutes this fact.

It is asserted in the rejection that claim 4 is not specific because there are too many gestagens to choose from. However, the Examiner is merely alleging or implying that the claim is too broad (which it is not). The breadth of a claim, in and of itself, does not establish lack of written description. The Examiner has not and cannot demonstrate that possession of the subject matter of claims 4 and 29 is not reasonably conveyed by Appellants' disclosure.

It is also argued that one of ordinary skill in the art can not tell the difference in effects that one gestagen may have in comparison to another. This assertion is irrelevant to the question of written description since it does not relate to the question of whether Appellants' disclosure reasonably conveys possession of the subject matter claimed. Nor does the Examiner provide any rationale as to why one of ordinary skill in the art would need to be able to tell the difference in effects between one gestagen in comparison to another. Such difference in effects can easily be determined by routine experimentation such as by following the examples in Appellants' specification using different gestagens.

3. Claim 3

One of the details that the Examiner alleges is not specified in claim 14 is the number of days to use in the claimed method. Claim 3, however, does provide more details in the

terms of duration than claim 14. Specifically, claim 3 recites second phase is 10 days long.

4. Claims 5 and 30

One of the other details that the Examiner alleges is not present in claim 14 is the amount of the compounds to use. Claims 5 and 30 specify the amount of gestagen to use in terms of milligrams per day. Thus, this argument is clearly not relevant with respect to claims 5 and 30.

5. Claim 15

As noted above, one of the details that the Examiner alleges is not recited in claim 14, is the number of days to use in the method. This argument is clearly not relevant to claim 15 since this claim specifically recites that the period is 28 days long.

6. Claim 22

One of the details that the Examiner asserts is not recited in claim 14 is the type of compounds to use. This argument is clearly not relevant to claim 22 which recites that the gestagen is levonorgestrel or gestodene.

7. Claim 23

As noted above, the Examiner alleges that claim 14 does not recite such details as the type of compounds used or their amount. These assertions are clearly not relevant with respect to claim 23 which specifies both the gestagens to use and the dosages thereof.

8. Claim 25

One of the details that the Examiner asserts is not recited in claim 14 is the type of compounds to use. This argument is clearly not relevant to claim 25 which recites that the gestagen is gestodene, levonorgestrel, desogestrel, 3-ketodesogestrol or a mixture thereof and the estrogen is estradiol.

9. Claims 26-28

As mentioned above, the Examiner alleges that claim 14 does not provide specifics on

duration. This allegation is clearly irrelevant with respect to claim 26 and its dependent claims 27 and 28. Claim 26 recites that the first phase contains 18-23 days and the second phase contains 5-10 days.

Rejection under 35 USC §112, first paragraph (Enablement)

Claims 3-7 and 14-30 are rejected under 35 U.S.C. § 112, first paragraph on grounds of alleged lack of enablement. Appellants' respectfully traversed.

1. Independent Claim 14 and dependent Claims 5, 6, 7, 15-21, 24, 26-28 and 30

At page 5 of the January 26, 2004 Office Action, under the heading "The state of the art," the Examiner asserts that the prior art of record shows that each combination and duration are critical. However, the prior art does not in fact show such a criticality. For example, Koninckx (US 5,827,843) describes a method which broadly utilizes at least one progestogen and at least one estrogen. As for duration, Koninckx merely discloses that there is a periodicity between two blood concentrations of estrogen and that this periodicity is generally less than 10 days. Further, Koninckx discloses that periodicity will depend on the types of progestogens and estrogens used and their dosages and, moreover, that periodicity and concentrations can be determined by routine experimentation. See, e.g., column 2, lines 10-26.

Jager (CA 2,00,438) also broadly refers to "progestogenic and oestrogenic substantce" for use in its disclosed method. See, e.g., page 4, lines 1-13. Gast (US 5,888,543) similarly refers broadly to progestins and estrogens in describing its method. See, e.g., column 6, lines 4-16. Also at page 5 of the Office Action, under the heading "The state of the art," the Examiner asserts that there is no data or showing for any combination. Appelants' have refuted this argument several times, and the Examiner has presented no rebuttal. Contrary to the Examiner's allegation, Appellants' specification provides more than adequate information such as examples of specific gestagens, natural estrogens, periods, phases, and amounts, to practice the invention using no more than routine experim entation. See, e.g., Appellants' specification at pages 6-7 and 9-13. In addition, in Appellants' examples 1-8 specific method embodiments are described that indicate durations, specific combinations, and amounts. Thus,

the assertion that "no data or showing" is provided is clearly wrong. Based on the information in Appellants' disclosure and the large amount of information available within this particularly well developed art, one of ordinary skill in the art can easily practice the claimed invention without undue experimentation.

Various combinations of gestagens and estrogens using different dosage regimes are well known within the art. See, e.g., the prior art of record, the discussions therein of the state of the art, and Appellants' disclosure at page 1-5. This is evidence of the well developed nature of the art and the large amount of past and ongoing research. Such a developed art facilitates routine experimentation.

Also under the heading "The state of the art," the Examiner asserts that "there is no description how every gestagen and estrogen combination would be useful." Firstly, it is noted that claim 14 does not recite any estrogen, but specifies that the estrogen is a natural estrogen. Moreover, Appellants' disclosure clearly describes the method using the terms gestagen and natural estrogen (see, e.g., page 6). An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. § 112 unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. See, e.g., *In re Brana, 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995), and *Fiers v. Revel, 984 F.2d 1164,* 24 USPQ2d 1601 (Fed. Cir. 1993).

At page 2 of the Office Action, it is asserted that "it is impossible to predict contraception" within the scope of Appellants' claims. This is not the test for enablement. Absolute predictability is not required under the statute. Instead, the issue is whether objectively one of ordinary skill in the art can practice the invention using no more the routine experimentation. The rejection presents no rationale to doubt the veracity of statements within Appellants' disclosure and no rationale as to why performing experimentation to practice the invention would be undue.

Under the heading "The predictability or lack thereof in the art," the Examiner argues that the pharmaceutical art exhibits a general lack of predictability and as a result "predicting which compounds within the broad genus will be useful is impossible." The allegation that the pharmaceutical art is generally unpredictable does not lead to a *per se* conclusion of undue

experimentation. Moreover, Appellants' specification does provide examples of specific gestagens, natural estrogens, periods, phases, and amounts. With such information, one of ordinary skill in this art can readily practice the invention using no more than routine experimentation.

In the rejection, *In re Fischer*, 166 USPQ 18 (CCPA 1970), is cited for the proposition that "there is generally a lack of predictability in the pharmaceutical art" and "therefore predicting which compounds within a broad genus would be useful is impossible." However, the relevant language *In re Fischer* is as follows:

> In cases involving unpredictable factors, such as most chemical reactions and physiological activities, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

Fischer does not hold for the implied proposition that, merely because there are unpredictable factors within an art, the art is necessarily not enabling. Nor does *Fischer* in anyway indicate that within pharmaceutical art in general, predicting which compounds within a broad genus would be useful is impossible. Furthermore, as mentioned above, absolute predictability is not a requirement for enablement.

The issues in *Fischer* focused on how to make certain compounds. In *Fischer*, the claimed invention was an ACTH (adrenocoritcotrophic hormone) preparation which comprised an active component of any polypeptide that contained at least 24 amino acids of a specified sequence. Also claimed was an ACTH preparation containing at least 1 international unit of ACTH per milligram. The Court held the disclosure to be insufficient to support these claims because the parent application did not inherently or expressly disclose polypeptides that contained more than 39 amino acids, although the claim included all polypeptides having the at least 24 amino acids in the specified sequence. In addition, the specification only disclosed products having potencies of 1.11 to 2.3 international units of ACTH activity per milligram, and the Court held that the record did not support ACTH preparations having potencies much greater than 2.3.

Fischer does not support an assertion of non-enablement with respect to Appellants' claimed invention. One or ordinary skill in the art is clearly objectively enabled as to how to make the compositions used within the claimed method. As noted above, various combinations of gestagens and estrogens for use in different dosage regimes are well known

within the art.

Under the heading "The amount of direction or guidance presented," the Examiner again cites *Fisher,* as well as *In re Wright,* 27 USPQ2d 1510 (Fed. Cir. 1993) and *In re Vaeck,* 20 USPQ2d 1438 (Fed. Cir. 1991). In addition, the Examiner alleges that no guidance is provided by Appellants' specification and that "it is not obvious from the disclosure of one species, what other species will work." As mentioned above, Appellants' specification provides more than adequate information such as examples of specific gestagens, natural estrogens, periods, phases, and amounts, to practice the invention using no more than routine experimentation. See, e.g., Appellants' specification at pages 6-7 and 9-13. Further, Appellants' examples 1-8 describe specific method embodiments are described that indicate durations, specific combinations, and amounts. These disclosures provide more than sufficient guidance to objectively enable one of ordinary skill in the art to use the claimed invention with no more than routine experimentation. The Examiner asserted "obvious" test is not one supported by any case law.

In re Vaeck, 20 USPQ 2d (Fed. Cir. 1991) and *In re Wright*, 27 USPQ 2d 1510 (Fed. Cir. 1993), both dealt with biotechnology inventions. In both cases, the fields of technology involved, gene expression in cyanobacteria cells and live, non-pathogenic vaccines for pathogenic RNA viruses, were just emerging and thus were not well developed.

Conversely, in the instant case, the field of oral contraception using gestagens and estrogens is a well established field of technology. As stated at page 1 of Appellants' specification, hormonal contraceptives have been known since the 1960's. One of ordinary skill in this relevant art is well aware of procedures, both in *in vivo* and *in vitro*, used for testing oral contraceptive preparations. Moreover, such examples are not needed to objectively enable one of ordinary skill in the art. See, for example, the disclosures of Konnicx, Gast and Jager, all of which disclose oral contraceptives using particular dosage regimens but do not present any *in vivo* or *in vitro* tests. By now it is well settled law that one of ordinary skill in the art need not disclose that which is well known in the art. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 231 USPQ 81 (Fed. Cir. 1986).

Thus, in vitro and in vivo test models are well known within this art. Determining the relative efficacy of any particular combination of gestagen and natural estrogen requires no more than routine experimientation. All that is required under the statue is objective enablement. It is

not required those Appellants' disclosure presents in vivo or in vitro test results. See, e.g., *In re Marzocchi et al.*, 169 USPQ 367, 369(CCPA 1971):

> The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

Also, it is by now well settled law that the test for enablement is not whether any experimentation is needed, but whether or not that experimentation is undue. See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976) in which the art involved (catalysis) was acknowledged to be unpredictable, yet the amount of experimentation needed for enablement was not undue. Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See, e.g., *Ex parte Jackson,* 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988).

In the Office Action, the Examiner quotes from *In re Dreshfield*, 45 USPQ 36 (CCPA 1940) and then asserts that a disclosure should contain representative examples. However, the language quoted by the Examiner refers to the enumeration of a number of members of a chemical group, not specific working examples. Appellants have enumerated members of the classes of gestagens and estrogens in the specification. Moreover, the members of these classes are well known to those of ordinary skill in the art.

The Examiner also cites *In re Riat et al.* 140 USPQ 473 (CCPA 1964). In *Riat*, the invention was concerned an organic water soluble dye stuff. The court held that the claims did comply with 35 USC § 112. There was no reason in the record to suggest that the compounds encompassed by the claims would not be useful as dyestuffs.

> We find no suggestion in the record of any compound encompassed by the generic claims which would not be a dyestuff. The appealed claims are drawn to azo dyes and the Examiner stated that "azo dyes are well known."

The rejection also refers to *In re Barr et al.* 170 USPQ 330 (CCPA 1971). In *Barr,* the Court reversed a rejection asserting that the claims were unsupported by the specification. Specifically, the court stated the following:

> Appellants have specifically disclosed how to make and use a large number of

compounds and asserted that other compounds similar to the compounds specifically disclosed in certain stated respects may be made and used in the same fashion. We see no reason, on the state of this record, to suspect that their assertion is not accurate or that appellants are not the pioneer inventors that they claim to be.

Thus, *Barr* is consistent with *Marzocchi*, i.e., that the burden is on the PTO to initially provide support for its challenge to the veracity of Applicant's statements of enablement within the disclosure, a burden which the present rejection does not satisfy.

In view of the above remarks, it is respectfully submitted that Appellants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with no more than routine experimentation. Reversal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

2. Claims 4 and 29

Claims 4 and 29 each recite that the gestagen is selected from a specific group of gestagens. In the rejection, the Examiner argues that the "claimed gestagens and estrogens are not limited," that the genus is broad, and that claim 14 recites any combination of gestagen and estrogen (which it does not). None of these arguments are applicable to claims 4 and 29 since these claims recite that the gestagen used with the natural is a member of a specific group of gestagens.

3. Claims 22 and 23

In the rejection, the Examiner argues that the "claimed gestagens and estrogens are not limited," that the genus is broad, and that claim 14 recites any combination of gestagen and estrogen (which it does not). None of these arguments are applicable to claims 22 and 23 which recite that the gestagen is levonorgestrel or gestodene.

5. Claim 25

In the rejection, the Examiner argues that the "claimed gestagens and estrogens are not limited," that the genus is broad, and that claim 14 recites any combination of gestagen and estrogen (which it does not). None of these arguments are applicable to claim 25

which recites that the gestagen is gestodene, levonorgestrel, desogestrel, 3-ketodesogestrol or a mixture thereof and the estrogen is estradiol.

Rejection(s) Under 35 USC §103 in view of Weiner et al.

Claims 3-7 and 14-30 are again rejected as being obvious in view Weiner at al. This rejection is once again respectfully traversed.

The following arguments were presented in the Reply file September 22, 2003. The Examiner has not responded to these arguments, but merely restated the rejection.

Weiner et al. disclose a treatment for contraception in which three silastic rods impregnated with 40 mg d-norgestrel are implanted in to the forearms of four patients are left in place for 100-458 days. After about 300 days of treatment, the patients were given a daily oral dose of 50 μg of ethynylestradiol, a synthetic steroid (see excerpt form The Merck Index, 11th Edition (1989)), for 21 days. Weiner et al. disclose that its synthetic estrogen increases the concentration of sex hormone binding globulin in plasma. Weiner et al. does not disclose that the dosage regime provides cycle control and regular menstrual bleeding.

At page 2 of the Final Office Action, it is argued that it "does not matter that the prior art uses a synthetic steroid because it teaches the same *method* as the presently claimed invention." This statement is at best confusing. First, it does matter. The prior art uses a synthetic estrogen and Appellants' method uses a natural estrogen. The prior art provides no suggestion or motivation to use a natural estrogen in its method. Further, the rejection makes no assertion of any motivation for so modifying the prior art. Motivation is a requisite showing for an obviousness rejection. Merely asserting, without rationale, explanation or support, that motivation is provided by the prior art does not establish that motivation exists.

Second, the prior art does not disclose the same method. For example, it uses a synthetic estrogen, not a natural estrogen. The Weiner et al. method would not have the characteristics/advantages associated with the use of a natural estrogen such fewer ethinyl estradiol-related side-effects. See, e.g., page 8, lines 1-19 of appellants' specification. Furthermore, the period of combined administration of d-norgestrel and ethynyl estradiol is 21 days, not 5-10 days.

Weiner et al. provide no suggestion of using other combinations of estrogens and gestagens. No other agents other than d-norgestrel and ethynyl estradiol are mentioned. Also,

Weiner et al. does not disclose or suggest any period for combined administration other than 21 days. The mere ability to modify a disclosure does not by itself establish obviousness. Instead, there most be some motivation established to modify the prior art. See, e.g., *In re Gordon,* 221 USPQ 1125, 1127 (Fed. Cir. 1984) and *In re Laskowski*, 10 USPQ 2d 1397, 1398 (Fed. Cir 1989). In the instant case, no such motivation is presented.

Weiner et al. fails to provide any motivation that lead one of ordinary skill in the art to modify the disclosed method to achieve a method having a dosage regimen (combination and dosage schedule) in accordance with the claimed invention. An assertion of obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. To assess this determination, the hypothetical person has the relevant prior art in from of him, but has **no knowledge of Appellants' invention**. Motivation is not established simply by assuming that the prior art can be modified. It is more than this. The establishment of motivation requires a rationale as to why one would be directed toward making particular modifications.

For the reasons discussed above, reversal of the rejection under 35 U.S.C. §103 is respectfully requested.

2. Claim 15

Weiner et al. disclose a "period" of about 321 days. No other period is disclosed or suggested by Weiner et al. Thus, Weiner et al. fails to render obvious the method of Appellants' claim 15 which specifically recites that the period is 28 days long.

3. Claim 16

Weiner et al. disclose that the gestagen d-norgestrel is administered separately from the estrogen ethynyl estradiol. No suggestion is provided by Weiner et al. that would lead one to administer the gestagen and estrogen in combination. Thus, Weiner et al. fails to render obvious the method of Appellants' claim 16.

4. Claims 19 and 21

Weiner et al. disclose that the gestagen d-norgestrel is administered transdermally while the estrogen ethynyl estradiol is administered orally. No suggestion is provided by

Weiner et al. that would lead one to administered. Weiner et al. provide no suggestion of administering the gestagen orally and administering the estrogen transdermally. Compare Appellants' claim 19. Similarly, Weiner et al. provide no suggestion of administering both the gestagen orally and the estrogen transdermally. Compare Appellants' claim 21

5. Claims 26-28

Weiner et al. disclose a "period" of about 321 days with a combination phase of 21 days. No other period is disclosed or suggested by Weiner et al. Thus, Weiner et al. fails to render obvious the methods of Appellants' claim 26 and its dependent claims 27-28. Claim 26 recites a first phase of 18-23 days and a second phase of 5-10 days.

(8) CONCLUSION

For all of the above reasons, it is urged that the decision of the Examiner rejecting claims 1-7 and 13-30, on appeal, is in error and should be reversed.

Respectfully submitted,

Brion Heaney
Registration No. 32,542

Filed: September 27, 2004

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Services as First Class Mail in an envelope addressed to: Commissioner of Patents, P O Box 1450, Alexandria, VA 22313-1450 on: 9/27/04
Name: R. Taylor
Signature: R. Taylor

CLAIMS APPENDIX

1. (Cancelled):

2. (Cancelled):

3. (Rejected): The method according to claim 14, wherein the second phase is the last 10 days of said at least 28 day period.

4. (Rejected): The method according to claim 14, wherein the gestagen is
gestodene,
progesterone,
levonorgestrel,
cyproterone acetate,
chloromadinone acetate,
drospirenone (dihydrospirorenone),
norethisterone,
norethisterone acetate,
norgestimate,
desogestrel,
3-ketodesogestrel,
dienogest,
or a mixture thereof.

5. (Rejected): The method according to claim 14, wherein the gestagen is
levonorgestrol at 0.05-0.2 mg/day,
gestodene at 0.05-0.15 mg/day,
or another gestagen in a bioequivalent dose.

6. (Rejected): The method according to claim 14, wherein the gestagen is administered orally and/or transdermally.

7. (Rejected): The method according to claim 14, wherein the natural estrogen is administered orally and/or transdermally.

8. (Cancelled):

9. (Cancelled):

10. (Cancelled):

11. (Cancelled):

12. (Cancelled):

13. (Cancelled):

14. (Rejected): A method of contraception in a female mammal, comprising administering to said mammal a gestagen over a period of at least 28 days, wherein said period has a first phase and a second phase,

wherein said first phase consists essentially of administering an ovulation-inhibiting amount of a gestagen, and said second phase comprises administering an ovulation-inhibiting amount of a gestagen and a natural estrogen in an amount effective to achieve regular menstrual-like bleeding,

wherein said second phase is the last 5 to 10 days of said period and said first phase is the remainder of said period.

15. (Rejected): The method of claim 14, wherein said period is 28 days.

16. (Rejected): The method of claim 14, wherein in the second phase, the gestagen

and natural estrogen are administered in combination.

17. (Rejected): The method of claim 14, wherein in the second phase, the gestagen and natural estrogen are administered separately.

18. (Rejected): The method according to claim 14, wherein the female mammal is human.

19. (Rejected): The method according to claim 14, wherein the gestagen is administered orally and the natural estrogen is administered transdermally.

20. (Rejected): The method according to claim 14, wherein the gestagen is administered transdermally and the natural estrogen is administered orally.

21. (Rejected): The method according to claim 14, wherein the gestagen and the natural estrogen are administered transdermally.

22. (Rejected): The method according to claim 14, wherein the gestagen is levonorgestrel or gestodene.

23. (Rejected): The method according to claim 14, wherein the gestagen is levonorgestrel in a dose of 0.05-0.2 mg/day, or
gestodene in a dose of 0.05-0.15 mg/day.

24. (Rejected): The method according to claim 14, wherein the gestagen and natural estrogen are each independently administered locally, topically, enterally, transdermally and/or parenterally.

25. (Rejected): The method according to claim 14, wherein gestodene, levonorgestrel, desogestrel, 3-ketodesogestrol or a mixture thereof is administered transdermally, and estradiol is administered transdermally at a dose of 0.025-0.25 mg of

release/day.

26. (Rejected): The method of claim 16, wherein
during the first phase, at least 18-23 first daily dosage units of a gestagen in an ovulation-inhibiting dose are administered, and
during the second phase, at least 5 to 10 second daily dosage units of a gestagen in an ovulation-inhibiting dose plus a natural estrogen are administered.

27. (Rejected): The method according to claim 26, wherein 28 daily dosage units are administered; during the first phase, 18 to 23 of said first daily dosage units of a gestagen are administered; and during the second phase, 5 to 10 of said second daily dosage units of a gestagen plus a natural estrogen are administered.

28. (Rejected): The method according to claim 26, wherein during the second phase, 10 daily dosage units of said gestagen plus estrogen are administered.

29. (Rejected): The method according to claim 16, wherein the gestagen in each phase, independently, is
gestodene,
progesterone,
levonorgestrel,
cyproterone acetate,
chloromadinone acetate,
drospirenone (dihydrospirorenone),
norethisterone,
norethisterone acetate,
norgestimate,
desogestrel,
3-ketodesogestrel,
dienogest,
or a mixture thereof.

30. (Rejected): The method according to claim 16, wherein the gestagen in each phase is, independently,
levonorgestrel in a dose of 0.1 mg/day,
gestodene in a dose of 0.075 mg/day, or
another gestagen in a bioequivalent dosage.

31. (Cancelled):

32. (Cancelled):

33. (Cancelled):

34. (Cancelled):

35. (Cancelled):

36. (Withdrawn): A method of contraception in a female mammal, comprising administering to said mammal a daily steroidal preparation over a period of at least 28 days, wherein

during the last 5-10 days of said period said mammal is daily administered a gestagen in an ovulation-inhibiting dose and a natural estrogen, and

during the rest of said period said mammal is daily administered a steroidal preparation consisting essentially of gestagen in an ovulation-inhibiting dose.

37. (Withdrawn): A method of contraception in a female mammal, daily comprising administering to said mammal a daily steroidal preparation over a period of at least 28 days, wherein

during the last 5-10 days of said period said mammal is daily administered a gestagen in an ovulation-inhibiting dose and a natural estrogen in an amount which is effective for

achieving regular menstrual-like bleeding, and

during the rest of said period said mammal is daily administered a steroidal preparation consisting essentially of gestagen in an ovulation-inhibiting dose.

38. (Withdrawn): A method of providing contraception in a female mammal comprising administering a daily steroid preparation to said female mammal for a period of 28 - 84 days and said period has a first phase and a second phase, wherein the second phase is the last 5 to 10 days of said period and said first phase is the remainder of said period,

wherein during said first phase a gestagen is daily administered in an ovulation inhibiting amount without an estrogen, and during said second phase a natural estrogen and an ovulation-inhibiting amount of a gestagen and are administered daily.

39. (Withdrawn): A method according to claim 38, wherein the second phase is the last 8 to 10 days of said 28 - 84 day period.

40. (Withdrawn): A method according to claim 38, wherein said period is 28 days.

41. (Withdrawn): A method according to claim 38, wherein said period is 56 days.

42. (Withdrawn): A method according to claim 38, wherein said period is 84 days.

43. (Withdrawn): A method according to claim 38, wherein the gestagen is
gestodene,
progesterone,
levonorgestrel,
cyproterone acetate,
chloromadinone acetate,
drospirenone (dihydrospirorenone),
norethisterone,
norethisterone acetate,
norgestimate,

desogestrel,
3-ketodesogestrel,
dienogest,
or a mixture thereof.

44. (Withdrawn): A method according to claim 38, wherein the gestagen is levonorgestrol at 0.05-0.2 mg/day or another gestagen in a bioequivalent dose.

45. (Withdrawn): A method according to claim 38, wherein the gestagen gestodene at 0.05-0.15 mg/day or another gestagen in a bioequivalent dose.

46. (Withdrawn): A method according to claim 38, wherein the gestagen is administered orally and/or transdermally.

47. (Withdrawn): A method according to claim 38, wherein the natural estrogen is administered orally and/or transdermally.

48. (Withdrawn): A method according to claim 47, wherein the natural estrogen is administered orally and/or transdermally.

49. (Withdrawn): A method according to claim 38, wherein in the second phase, the gestagen and natural estrogen are administered in combination.

50. (Withdrawn): A method according to claim 38, wherein in the second phase, the gestagen and natural estrogen are administered separately.

51. (Withdrawn): A method according to claim 38, wherein the female mammal is human.

52. (Withdrawn): A method according to claim 38, wherein the gestagen is administered transdermally and the natural estrogen is administered orally.

53. (Withdrawn): A method according to claim 38, wherein the gestagen is levonorgestrel or gestodene.

54. (Withdrawn): A method according to claim 38, wherein the gestagen is levonorgestrel in a dose of 0.05-0.2 mg/day or gestodene in a dose of 0.05-0.15 mg/day.

55. (Withdrawn): A method according to claim 38, wherein gestodene, levonorgestrel, desogestrel, 3-ketodesogestrol or a mixture thereof is administered transdermally, and estradiol is administered transdermally at a dose of 0.025-0.25 mg of release/day.

56. (Withdrawn): A method of providing contraception in a female mammal comprising administering a daily steroid preparation to said female mammal for a period of 28 - 84 days, said period having a first phase and a second phase, wherein the second phase is the last 5 to 10 days of said period and said first phase is the remainder of said period,

wherein during said first phase a gestagen is daily administered in an ovulation inhibiting amount and the daily amount of gestagen administered remains the same throughout the period, and during said second phase a natural estrogen and an ovulation-inhibiting amount of a gestagen are administered daily.

57. (Withdrawn): A method according to claim 14, wherein the gestagen is administered orally and / the natural estrogen is administered orally.

58. (Withdrawn): A method according to claim 36, wherein the gestagen is administered orally and / the natural estrogen is administered orally.

59. (Withdrawn): A method according to claim 37, wherein the gestagen is administered orally and / the natural estrogen is administered orally.

60. (Withdrawn): A method according to claim 38, wherein the gestagen is

administered orally and / the natural estrogen is administered orally.

61. (Withdrawn): A method according to claim 56, wherein the gestagen is administered orally and / the natural estrogen is administered orally.

62. (Withdrawn): A method according to claim 14, wherein there is a menstrual bleeding at the end of said period.

63. (Withdrawn): A method according to claim 36, wherein there is a menstrual bleeding at the end of said period.

64. (Withdrawn): A method according to claim 37, wherein there is a menstrual bleeding at the end of said period.

65. (Withdrawn): A method according to claim 38, wherein there is a menstrual bleeding at the end of said period.

66. (Withdrawn): A method according to claim 56, wherein there is a menstrual bleeding at the end of said period.

67. (Withdrawn): A method according to claim 14, wherein the second phase is the last 8 to 10 days of said period.

68. (Withdrawn): A method according to claim 14, wherein said period is 28-84 days.

69. (Withdrawn): A method according to claim 14, wherein said period is 28-56 days.

70. (Withdrawn): A method according to claim 14, wherein said method consists essentially of administering to said mammal, during said first phase, an ovulation-inhibiting amount of a gestagen, and, during said second phase, administering an ovulation-inhibiting amount of a gestagen and a natural estrogen in an amount effective to achieve regular

menstrual-like bleeding.

71. (Withdrawn): A method according to claim 70, wherein said natural estrogen is estradiol and said gestagen is
gestodene,
progesterone,
levonorgestrel,
cyproterone acetate,
chloromadinone acetate,
drospirenone (dihydrospirorenone),
norethisterone,
norethisterone acetate,
norgestimate,
desogestrel,
3-ketodesogestrel,
dienogest,
or a mixture thereof.

72. (Withdrawn): A method according to claim 70, wherein said period is 28-84 days.

73. (Withdrawn): A method according to claim 70, wherein said period is 28-56 days.

74. (Withdrawn): A method according to claim 71, wherein said first phase is 18-23 days.

75. (Withdrawn): A method according to claim 71, wherein said period is 28-84 days.

76. (Withdrawn): A method according to claim 71, wherein said period is 28-56 days.

77. (Withdrawn): A method according to claim 71, wherein said first phase is 18-23 days.